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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,904	11/30/2001	Harold R. Garner	UTSW:1045RCE	4132
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CHALKER FLORES, LLP 2711 LBJ FRWY Suite 1036 DALLAS, TX 75234			EXAMINER RIGGS II, LARRY D	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 01/09/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/998,904	<b>Applicant(s)</b> GARNER ET AL.	
	<b>Examiner</b> Larry D. Riggs II	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-7,9-42,44-53,56,57,203 and 204 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,9-42,44-53,56,57,203 and 204 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 October 2007 has been entered.

Applicant's amendments filed 15 October 2007 are acknowledged and the amendments are entered.

### ***Status of Claims***

Claims 1-3, 5-7, 9-42, 44-53, 56-57, 203 and 204 are currently pending and under consideration.

The indicated allowability of claims in the previous Office action mailed 15 June 2007 is withdrawn in view of the newly applied rejections below:

### ***Withdrawn Rejections/Objections***

The objection to claims 11, 13-21 and 23-36, in the Office action mailed 15 June 2007 is withdrawn in view of the amendments filed 15 October 2007.

The rejection of claims 18-20, 23, 26 and 30-36 under 35 U.S.C. 112, 1<sup>st</sup> Paragraph, in the Office action mailed 15 June 2007 is withdrawn in view of the amendments filed 15 October 2007.

The rejection of claims 11, 13-21 and 23-36 under 35 U.S.C. 112, 2<sup>nd</sup> Paragraph, in the Office action mailed 15 June 2007 is withdrawn in view of the amendments filed 15 October 2007.

### ***Specification***

The amendment filed 15 October 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

New paragraph 0072.1 provides "SNIDE provides a method for predicting one or more locations of single nucleotide polymorphisms..." While the previously presented claim 1, filed 03 April 2007, discloses the matter listed in the new paragraph 0072.1, and the specification provides the SNIDE algorithm as a point mutation prediction tool, (see specification, paragraph 76); the specification does not support "SNIDE providing a method" of all steps in the new paragraph 0072.1.

New paragraph 0072.2 provides "Alternatively, the calculated variation frequency can be adjusted, modified or reclassified..." Previously presented claims 22-36, filed 03 April 2007, recite the limitation "the step of adjusting the calculated variation

frequency..." in lines 1-2 of the claim 22 for example. However, the specification does not support the variation frequency being modified or reclassified.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7, 9-42, 44-53, 56-57, 203 and 204 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 in line 7 and claim 57 in lines 1-2, claim 203 in line 8, recite the limitation "one or more groups". The limitation does not have clear antecedent basis. One skilled in the art would be unclear as to what groups are being compared to the matrix considering only a single group of bases was recited in lines 3-4 of the instant claim 1.

Claims 1 in lines 8 and 10, claim 57 in line 3, claim 203 in line 9, recite the limitation "the bases". The limitation does not have clear antecedent basis as to which base the variation value is to be assigned or being identified, considering a first base, second base and group of bases are recited earlier in lines 3-4 of the instant claim 1.

Claim 1 in line 11 recites the limitation "will likely occur". The metes and bounds of the limitation are unclear. While the specification provides "The SNIDE algorithm may not necessarily predict all the possible mutations, but rather, likely mutations, e.g. CGA to TGA transitions", (see specification, paragraph 75, line 1); it is unclear if the

limitation "likely occur" pertains only to those mutations of CGA to TGA transition, or if other transitions would be considered possible mutations.

Claim 48 recites the limitation "comprises a mutant gene dataset that comprises all mutant genes in a mutant gene database minus the known mutant genes of the mutant gene dataset" in lines 2-3. The metes and bounds of the limitation are unclear. One skilled in the art would not know which mutant genes are in the mutant gene dataset if all known mutant genes are not included, and how it is known if the genes that are included in the mutant gene database are actually mutant genes.

Claim 57 recites the limitation "the bases" in lines 8 and 10. The limitation does not have clear antecedent basis as to which base the variation value is to be assigned or being identified, considering a first base, second base and group of bases are recited earlier in lines 3-4 of the instant claim.

Claim 204 in lines 8-9, recite the limitation "comparing the wild-type gene sequence one or more codons at a time". The metes and bounds of the limitation are unclear. One skilled in the art would be unclear as which codons are to be compared to the matrix at what time, what order of codons are to be compared to the matrix or what the timing of comparing codons to a matrix has any bearing on the prediction of variations of the sequence.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 5-7, 9-42, 44-53, 56-57, 203 and 204 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a method and a computer program for predicting one more locations of single nucleotide polymorphisms in a nucleic acid sequence.

In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 1-3, 5-7, 9-42, 44-53, 56-57 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of the database to produce a real-world result. The instant claims are drawn to a method

of predicting SNPs in a nucleic acid sequence. However, the last step of the claims include outputting the identified locations of the single nucleic acid polymorphisms but neither the instant claim nor the specification provide in what form the data is outputted or to where the data is outputted. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claims 203 and 204 are drawn to a computer readable medium comprising a computer program for predicting one or more locations of variations in a sequence. While the instant specification does not explicitly define the scope of the limitation of "computer readable medium," one skilled in the art would understand that computer readable medium includes carrier wave, which is a signal. For example, Fiekowsky et al., in US patent 6,090,555 (Date of Patent: July 18, 2000), define computer readable medium as being "a CD-ROM, floppy disk, tape, flash memory, system memory, hard drive, and a data signal embodied in a carrier wave." See column 14, claim 12. Bornstein et al., in US patent 6,144,388 (Date of patent : Nov. 7, 2000) state, "The computer readable medium of the present invention generally includes a tape, a floppy disk, a CD ROM, a carrier wave. In a preferred embodiment, however, the computer readable medium of the present invention is a carrier wave." See column 8, lines 33-37.



Therefore, at least one embodiment of the instant claims 203 and 204 are drawn to carrier wave or a signal encoded thereon a computer program.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. The following analysis on why such a signal encoded with functional descriptive material is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at <http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm>):

*First, a claimed signal is clearly not a "process" under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures "relate to structural entities and can be grouped as 'product' claims in order to contrast them with process claims." 1 D. Chisum, Patents §1.02 (1994). The three product classes have traditionally required physical structure or material.*

*"The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.*

*A "composition of matter" "covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff'd, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.*

*The Supreme Court has read the term "manufacture" in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.*

A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that a manufacture was also intended to require physical matter. A signal, a form of energy, does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.

*These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.*

Thus, claims 203 and 204 are drawn to nonstatutory subject matter.

### **Conclusion**

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry D. Riggs II whose telephone number is 571-270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/  
Larry D. Riggs II  
Examiner, Art Unit 1631

/ Shubo (Joe) Zhou/  
Shubo (Joe) Zhou, Ph.D.  
Primary Examiner